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| 10/557,280 | 11/18/2005 | Lawrence J. Wangh | 038519-0304 | 8830 |
| 22428 | 7590 | 01/24/2008 | EXAMINER | |
| FOLEY AND LARDNER LLP | | | BERTAGNA, ANGELA MARIE | |
| SUITE 500 | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/557,280 | WANGH ET AL. |
| | Examiner | Art Unit |
| | Angela Bertagna | 1637 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01 November 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 39-66 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 39-66 is/are rejected.
 7) Claim(s) 48-54 and 59-66 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Applicant's response filed on November 1, 2007 is acknowledged. Claims 39-66 are currently pending. In the response, Applicant canceled claims 1-38 and presented new claims 39-66.

Applicant's cancellation of claims 1-38 and submission of new claims 39-66 overcomes the following rejections: (1) rejection of claims 12-23, 37, and 38 under 35 U.S.C. 112, second paragraph, (2) rejection of claims 1-9, 12, 13, and 37 under 35 U.S.C. 102(b) as being anticipated by Vodkin as evidenced by Barbeau, (3) rejection of claims 1-6, 8-13, and 37 under 35 U.S.C. 102(b) as being anticipated by Thornhill as evidenced by Barbeau and Builder, (4) rejection of claims 14-19 under 35 U.S.C. 103(a) as being unpatentable over Thornhill in view of Barbeau and further in view of Builder and further in view of Harvey, (5) rejection of claims 17-23 under 35 U.S.C. 103(a) as being unpatentable over Thornhill in view of Barbeau and further in view of Builder and further in view of Pourahmadi, and (6) rejection of claim 38 under 35 U.S.C. 103(a) as being unpatentable over Thornhill in view of Barbeau and further in view of Builder.

Accordingly, these rejections have been withdrawn.

Claim Objections

2. Claims 48-54 and 59-66 are objected to because of the following informalities: It appears that claims 48 and 52 contain typographical errors. In claim 48, it would appear that "step b)" was intended for "step a)". In claim 52, it would appear that "or a microtiter plate cover" was

intended in line 2. Claims 49-51, 53, 54, and 59-66 are objected to since they depend from claims 48 and 52.

Appropriate correction or clarification is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39-66 are indefinite, because independent claim 39 recites "a chaotropic salt having a concentration of at least 2M that denatures or degrades all proteins, including nucleases". The phrase "including nucleases" is exemplary claim language that causes the scope of the claims to be unclear (see MPEP 2173.05), and as a result, the claims are indefinite. Amendment of the claims to delete the phrase "including nucleases" would overcome this rejection.

Allowable Subject Matter

4. Claims 39-66 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: The instant claims are drawn to a method for performing RT-PCR using a sample that has been

lysed (i.e. disrupted) with a chaotropic salt and diluted prior to the amplification steps. The method prohibits separating the RNA from the chaotropic salt and degraded or denatured proteins before conducting RT-PCR. The closest prior art is that of Vodkin et al. (BioTechniques (1994) 17(1): 114-116; cited previously), Pasloske et al. (US 6,777,210 B1; newly cited), and Harvey et al. (US 5,939,259; cited previously). The Vodkin and Pasloske references teach performing RT-PCR using diluted lysates prepared by detergent lysis (page 114 of Vodkin) or thermal lysis (columns 13-14 of Pasloske), and therefore, do not teach or suggest the claimed methods where a chaotropic salt, which is known to inhibit the activity of reverse transcriptase, is used for lysis. Harvey teaches DNA isolation from filter paper impregnated with chaotropic salts (columns 5-6), but this method requires washing steps and does not suggest that more delicate RNA molecules can be isolated and subsequently amplified using the method.

Double Patenting

5. Applicant is advised that should claim 42 be found allowable, claim 55 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

6. No claims are currently allowable. Claims 39-66 are free of the art, as noted in section 4 above, but they have been rejected for other reasons, specifically failure to comply with 35 U.S.C. 112, second paragraph.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is 571-272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMS
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KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

1/22/08